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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,236	03/11/2004	Abhay Sharma	U 015074-0	3561

7590

09/15/2006

Ladas & Parry  
26 West 61 Street  
New York, NY 10023

EXAMINER
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PERREIRA, MELISSA JEAN

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/798,236

Applicant(s)

SHARMA, ABHAY

Examiner

Melissa Perreira

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 2 and 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in WO on 12/29/03. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

### ***Oath/Declaration***

The incorrect box (b) stating the specification identification was marked. The correct box (a), for new, nonprovisional applications should have been check to designate that the specification is attached hereto. Please make the appropriate corrections.

### ***Specification***

### ***Claim Objections***

2. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The subject *Drosophila melanogaster* does not further limit the independent claim 1 which states, "culturing *Drosophila melanogaster*".

3. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

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dependent form, or rewrite the claim(s) in independent form. The statement that the altered height climbed under drug treatment and an altered speed after drug withdrawal are the characteristics of neuroactive compounds does not further limit claim 1 which states, " (f) the height climbed, climbing speed and distance walked, wherein an alteration in either.....drug treated males or (i) after drug withdrawal is characteristic or indicative of neuroactive compounds".

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma et al. (US 2002/0114855A1) in view of the combined disclosures of Greenspan (US 6,551,575B1), Hirsh et al. (US 5,711,932) and Wolfner et al. (US 6,380,159B1).

6. Sharma et al. (US 2002/0114855A1) discloses the use of *Drosophila melanogaster* as a model for screening materials useful as psychostimulants whereby plant materials are screened for their efficacy as CNS depressants/stimulants and the extracts may be used to treat depression and hyperactivity disorders. (p1, [0001] and [0011]). The method of detection of the analeptic and psychostimulant properties of the extracts involves observing spontaneous locomotor activity in differently treated flies. Also disclosed is the use of standard methods for growing *Drosophila melanogaster*

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cultures on medium, such as maize powder, sugar, yeast and Nipagin at room temperature. The male flies of similar age were used and the experimental conditions were kept identical throughout and the neuroactivity of the substance in question can be detected in the fruit fly do to the amenable genetic make up of the flies (p2, [0015], [0019], [0025] and [0028]; p4, [0038]). Sharma et al. (US 2002/0114855A1) does not disclose the culture medium of the instant claims or examination of the geotaxis activity of the flies upon treatment of the flies with neuroactive drugs.

7. Greenspan (US 6,551,575B1) discloses the method of administering, by ingestion, a test compound to an invertebrate, such as *Drosophila melanogaster* and measuring a geotactic behavior of the invertebrate for identifying compounds that modulate a mammalian vestibular system. The method consists of obtaining a first a second strain of invertebrate; subjecting the first and second invertebrate strains to conditions in which the first strain exhibits a geotactic behavior different than the geotactic behavior exhibited by the second strain (column 1, line 62+; column 6, line 15). Geotactic behavior can be manifested by crawling, walking or flying in a specific direction and/or orientation in response to the force vector of gravity. The invertebrate having a walking pattern characterized as negative geotactic behavior walks in the opposite direction as the force vector (column 5, lines 31+).

8. Hirsh et al. (US 5,711,932) discloses the method of testing neuroactive agents on cellular receptors of decapitated *Drosophila melanogaster* and examination of the locomotion response of the flies. Drug application may consist of the neuroactive agents

directly applied to the severed nerve cord of the invertebrate or an alternative means, such as injection into intact animals (column 1, lines 61+; column 2, lines 40-41; fig 1).

9. Wolfner et al. (US 6,380,159B1) discloses fly handling and rearing where wild type *melanogaster* were maintained on yeast-glucose media at room temperature and collected within 10 h or eclosion. Flies were kept in fresh vials isolated from the opposite sex (column 23, example 1).

10. At the time of the invention it would have been obvious to one ordinarily skilled in the art to combine the disclosure of Sharma et al. (US 2002/0114855A1) and/or Hirsh et al. (US 5,711,932) to study the geotaxis activity of the *Drosophila melanogaster* after treatment with the drugs and after drug withdrawal as is seen in Greenspan (US 6,551,575B1). The substitution of the neuroactive drug for a compound that modulates a mammalian vestibular system would be obvious since they both would affect the locomotor and geotaxis activity for example, by causing dizziness in the case of the mammalian vestibular system. The inclusion of the polysaccharide agar-agar into the culture medium of Sharma et al. (US 2002/0114855A1) would be obvious since it is a well-known culturing material for microbiological work. The gelatinous consistency would be useful to keep the culture medium immobile in the testing vials.

### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. US 7,005,297 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both are a method for screening neuroactive substances in male *Drosophila melanogaster* of the age group of 2-4 days. Further subjecting the group of male flies to geotaxis and locomotor activity assays is encompassed by both the instant application and the U.S. Patent No. US 7,005,297 B2 as is the medium for culturing the flies.

### **Conclusion**


No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP  
August 28, 2006

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER